IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	KARL BRUCE THOR
Serial No.:	10/049,427
Patent No.	7,718,705
Filed:	MAY 6, 2002
Issued:	MAY 18, 2010
Atty. File No.:	4220-78-PUS
For:	METHODS OF USING RAPID-ONSET SELECTIVE SEROTONIN REUPTAKE INHIBITORS FOR TREATING SEXUAL DYSFUNCTION

Group Art Unit:	1617
Examiner:	YONG SOO CHONG
Conf. No.:	1087

RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.705(d)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

1. This statement is respectfully submitted in accordance with 37 C.F.R. § 1.322 in response to the Decision on Request for Reconsideration of Patent Term Adjustment mailed October 20, 2010 (hereinafter "Decision") and in further support of the "Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(d)" for the above-referenced patent. While the Applicant believes that no additional fees are due with the filing of this Response to Decision on Request for Reconsideration Under 37 C.F.R. § 1.705(d), the undersigned hereby authorizes the charge of any fees deemed necessary to Deposit Account No. 19-1970.

2. An Application for Patent Term Adjustment ("Application") was filed on July 16, 2009, requesting recalculation of patent term adjustment indicated as reported with the

Notice of Allowance. The Decision granted-in-part and denied-in-part the relief sought in the Application.

3. Applicant appreciates the Supervisor's continued attention to this matter and acknowledges that the Decision modified the patent term adjustment from a previously granted 724 days to 1227 days. However, in view of the following, it is respectfully requested that Applicant be granted a patent term adjustment of 1,335 days.

I. THE "B DELAY" TO COMPRISES 511 DAYS

4. For reference, a brief summary of relevant dates in this matter is provided below:

March 3, 2002: 35 U.S.C. 371 date
March 3, 2005: 3 years from 371 date
April 4, 2006: Notice of Appeal Filed
July 28, 2006: Request for Continued Examination Filed

5. As further provided in the foregoing, the 115 days from April 4, 2006 to July 28, 2006 should properly be counted under 35 U.S.C. 154(b)(1)(B) ("B delay").

6. The Decision improperly states that the B delay period "does not include the number of days beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31, and ending on the day before the RCE was filed, or 115 days." In support of this argument, the Decision apparently relies upon 35 U.S.C. 154(b)(1)(C)(iii). The relevant text of this statute is reproduced below for reference:

> (C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to-
>
> > (iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

From the plain words of the statute, 35 U.S.C. 154(b)(1)(C)(iii) pertains to delays due to appeals and similar matters, often referred to as "C delay." However, at issue in the

present case is the extent of B delay. Applicant therefore submits that reliance on 154(b)(1)(C)(iii) is misplaced and improper and does not operate to limit the patent term extension owed to Applicant under 35 U.S.C. 154(b)(1)(B).

In addition, the provisions of 154(b)(1)(C)(iii) have not been satisfied. With respect to the Notice of Appeal filed April 4, 2006, no appellate review by the Board or a Federal court occurred and no determination of patentability was made.

7. The relevant provision for determining patent term adjustment in this case, 35 U.S.C. 154(b)(1)(B) contemplates a patent term adjustment of 511 days under B delay. The relevant portions of 35 U.S.C. 154(b)(1)(B) are reproduced below.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-
>
> (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
>
> (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or
>
> (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(Emphasis added). Section (i) provides the expiration date for B delay in this case. In accordance with the plain language of this statute, B delay is limited by any time consumed by continued examination of the application. See 35 U.S.C. 154(b)(1)(B)(i). Thus, Applicant's filing of the Request for Consideration ("RCE") on July 28, 2006 tolls the period of B delay and the B delay term runs from March 4, 2005 to July 27, 2006 and is **511** days.

8. 35 U.S.C. § 154(b)(1)(B)(ii) clearly does not apply. By its own rule, 37 C.F.R. § 41.35, the USPTO acknowledges that jurisdiction does not pass to the Board until after all briefs and examiner's answer have been entered. In this case, the Notice of Appeal filed April 4, 2006 was not submitted to the Board, no Appeal Brief or Examiner Answer was filed, and therefore no "appellate review" occurred.

II. APPLICANT UNDERTOOK BEST EFFORTS TO CONCLUDE PROSECUTION

9. 35 U.S.C. § 154(b)(1)(B)(iii) is similarly inapplicable. The Director has prescribed regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Under 37 C.F.R. § 1.704(b), an applicant is deemed to have failed to engage in reasonable efforts to conclude examination where an excess of three months is taken to reply to a notice or action by the Office. Additional circumstances considered to be a failure to engage in reasonable efforts are enumerated in § 1.704(c). Notably absent from § 1.704, however, is the filing of a Notice of Appeal.

10. It is further noted that review of the patent at issue was conducted by three different examiners, with the change from the second to the third examiner occurring at a critical time in the prosecution of the application. While Applicant acknowledges that there is no guarantee of examiner-continuity, this PTO's imposition of a third examiner was a driving force in Applicant' decision to pursue an RCE subsequent to the first Notice of Appeal. (*See* Declaration of Nadine Chien, ¶¶ 4, 9.)

11. Most notably, Applicant first became aware of the assignment of a *third* Examiner in the present case, Yong Soo Chong, subsequent to the filing of a Notice of Appeal having a filing date of April 4, 2006. (Chien Dec., ¶ 6). Had the second Examiner, Gregory Mitchell, who issued the final office action remained assigned to the application, Applicant would have completed the original appeal process initiated on April 4, 2006 as Applicant would have had no expectation that an RCE would have yielded issuance of the application by Examiner Mitchell. (Chien Dec., ¶ 9). However, to the surprise of Applicant, new Examiner Chong and his supervisor, Examiner Wang, authorized an in-

person interview on June 8, 2006. In attendance on behalf of Applicant were Ms. Nadine Chien, Ph.D., Mr. David Rivas, M.D., Mr. Joe Kentoffio and Mr. Gary Connell.

12. During the course of the interview, the propriety of rejections under 35 U.S.C. § 103(a) were discussed with respect to the McMahon reference (*J. Urology*, 161, 1826-30). Applicant maintained and did not waiver from their position that Examiner Mitchell had misconstrued the McMahon reference. Upon discussing the rejections with the newly appointed Examiner, Applicant deemed it appropriate to file the Request for Continued Examination on July 28, 2006 to permit Examiner Chong to familiarize himself with the application and the McMahon reference. Applicant also were of the expectation that this would actually result in a more expedited handling of the application (Chien Dec., ¶¶ 9, 10).

12. In light of the inconsistency presented to the Applicant through Examiner replacement, a situation over which Applicant had no control, Applicant pursued the present case in the most diligent and expeditious manner possible (Chien Dec., ¶¶ 9, 10).

III. RECENT FEDERAL CIRCUIT PRECEDENT SUPPORTS APPLICANT'S POSITION

In *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the Federal Circuit Court of Appeals examined and addressed the legislative history of the 1999 amendments to 35 U.S.C. § 154(b) under the American Inventors Protection Act. While first noting that only a most extraordinary showing of contrary intention by Congress would support a deviation from the plain language of a statute, the Court noted that the legislative history of the 1999 Act in fact supports a plain reading of the statutory language as written. Specifically, the relevant language from the AIPA's section-by-section analysis states:

> "no patent applicant diligently seeking to obtain a patent will receive a term of *less than the 17 years* as provided under the pre-GATT standard; *in fact, most will receive considerably more*."

Wyeth v. Kappos, 591 F.3d at 1371 (citing H.R.Rep. No. 106-464, at 125 (1994)).

In this case, the plain language of the relevant statute, 35 U.S.C. 154(b)(1)(B)(i), provides that the B delay period runs until the filing of the RCE on July 28, 2006. Accordingly, Applicant is entitled to 511 days of B delay as calculated from the date is three years after the date on which the national stage commenced and ending on the date the patent was issued, but not including the number of days beginning on the date on which the RCE was filed.

IV. CONCLUSION

No basis has been provided for the exclusion of 115 days between the filing of a Notice of Appeal on April 4, 206 and the filing of an RCE on July 28, 2006. Rather, 35 U.S.C. 154(b)(1)(B) requires that this period be included in the Patent Term Adjustment. Accordingly, Applicant submits that the appropriate Patent Term Adjustment is as follows:

Three year delay		511 days
Examination delay	1.702(a) and 1.703(a)(6)	183 days
Applicant delay		(76 days)
Overlap		(7 days)[1]
Total		611 days

[1] Applicant acknowledges that the exclusion of this overlap period is contingent upon the currently disputed duration of B delay and, pending issues addressed herein, may be subject to change.

The Total PTA is therefore the sum of 724 days as calculated in the Decision, plus 611 days as calculated above, a total of 1,335 days.

In accordance with 37 C.F.R. § 1.705(b)(2)(iii), Applicant states that the above identified application is not subject to a terminal disclaimer.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **1,335 days.**

Respectfully submitted,

SHERIDAN ROSS P.C.

By: /James M. Burke/
James M. Burke
Registration No. 66,445
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

Date: November 12, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)
KARL BRUCE THOR	) Group Art Unit: 1617
Serial No.: 10/049,427	) Examiner: YONG SOO CHONG
Issued Patent No.: 7,718,705	) Confirmation No.: 1087
Filed: May 6, 2002	) DECLARATION OF NADINE CHIEN IN
Issued: May 18, 2010	) RESPONSE TO DECISION FOR REQUEST
Atty. File No.: 4220-78-PUS	) FOR RECONSIDERATION UNDER 37 C.F.R. § 1.705(d)
For: "METHODS OF USING RAPID-ONSET SELECTIVE SEROTONIN REUPTAKE INHIBITORS FOR TREATING SEXUAL DYSFUNCTION"	) Filed Electronically

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The undersigned, Nadine Chien, Ph.D., Esq., hereby declares as follows:

1. I am the Vice President of Legal Affairs for Furiex Pharmaceuticals, Inc., a Delaware corporation ("Furiex").

2. The named inventor of the above-referenced patent is Karl Bruce Thor. The Assignee of the above-referenced patent, as evidenced by USPTO assignment records, is APBI Holdings, LLC ("APBI").

3. APBI is a wholly owned subsidiary of Furiex. Due in part to APBI's relationship with Furiex and my position at Furiex, I was substantively involved in decision making with respect to the above-referenced application and resulting patent.

4. Through no fault of the Applicant, prosecution of the above referenced application was handled by three different examiners at the USPTO. This turnover in examiners was a driving force in Applicant's decision to pursue a Request for Continued Examination on July 28, 2006, subsequent to the filing of a Notice of Appeal on April 4, 2006.

5. On April 4, 2006, Applicant filed a Notice of Appeal. It was Applicant's position that Examiner Mitchell's final rejection of the pending claims as unpatentable under 35 U.S.C. § 103(a) based upon the McMahon reference (J. Urology, 161, 1826-30) was incorrect. It was Applicant's position that Examiner Mitchell was interpreting the McMahon reference improperly.

6. At the time the Notice of Appeal was filed, Applicant believed Examiner Mitchell was still assigned to handle the application. Only after the Notice of Appeal was filed did Applicant learn that a new examiner, Examiner Chong, was assigned to the application.

7. On June 8, 2006, I attended an Examiner-Applicant interview at the U.S. Patent Office regarding the above-referenced application with Examiner Chong and his supervisor, Examiner Wang. Also in attendance on behalf of Applicant was Mr. David Rivas, M.D., Mr. Joe Kentoffio, and Mr. Gary Connell.

8. During the course of the interview on June 8, 2006, the propriety of rejections under 35 U.S.C. § 103(a) were discussed with respect to the McMahon reference. Applicant maintained and did not waiver from its position that a previous examiner, Examiner Mitchell, had misconstrued the McMahon reference.

9. Upon discussing the rejections with the newly appointed Examiner, Applicant deemed it appropriate to file a Request for Continued Examination on July 28, 2006 to permit Examiner Chong to familiarize himself with the application and the McMahon reference. Applicant would not have filed the RCE but for the appointment of a third examiner to the case. Applicant was of the expectation that allowing Examiner Chong additional time to consider Applicant's position outside the context of an appeal and without having to prepare an Examiner's Appeal Brief on unfamiliar matters would actually result in a more expedited and favorable handling of the application.

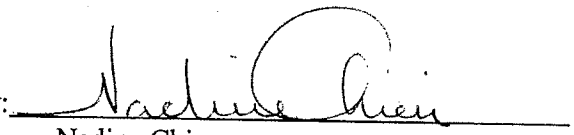
10. Applicant pursued the present case in the most diligent and expeditious manner possible. Applicant's decision to file the above-referenced RCE subsequent to a Notice of Appeal

was a further attempt of Applicant to diligently prosecute this case in light of changed circumstances presented by the USPTO.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: November 12, 2010

By: 

Nadine Chien
Furiex Pharmaceuticals, Inc.
3900 Paramount Parkway
Suite 150
Morrisville, NC 27560